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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,188	05/11/2001	Paul R. Findell	3930-0911	7236

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FIBROGEN, INC.  
Intellectual Property Department  
225 Gateway Blvd.  
South San Francisco, CA 94080

EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/854,188

Applicant(s)

FINDELL ET AL.

Examiner

Regina M. DeBerry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 36 in part, drawn to a method of treating glioma comprising administering to a subject in need an effective amount of an agent that effects processing of laminin 5 by BMP-1, class dependent on agent.
- II. Claims 1, 2, 4-10, 14, 36 in part, drawn to a method of treating squamous cell carcinoma, comprising administering to a subject in need an effective amount of an agent that affects processing of laminin 5 by a BMP-1 related protein or BMP-1, class dependent on agent.
- III. Claims 1,2, 4-9, 11-14, 36 in part, drawn to a method of treating squamous cell carcinoma, comprising administering to a subject in need an effective amount of an agent that affects processing of laminin 5 by a BMP-1 related protein or mTld, class dependent on agent.
- IV. Claims 15-17, drawn to a composition comprising an agent that affects processing of laminin 5 by a BMP-1 related protein and an acceptable carrier, class dependent on agent.
- V. Claims 18-24, drawn to a method of diagnosing a condition comprising detecting the expression of a BMP-1 related protein in a sample, classified in class 436, subclass 501.
- VI. Claim 25 drawn to a diagnostic kit, classified in class 435, subclass 7.1.

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- VII. Claims 26, 31 drawn to a method of screening for an agent that affects the processing of laminin 5 by BMP-1 related proteins, classified in class 435, subclass 7.92.
- VIII. Claims 27, 32-35, drawn to an isolated polypeptide comprising a BMP-1 cleavage sequence, classified in class 530, subclass 300.
- IX. Claims 28-29, drawn to the isolated polynucleotide, classified in class 536, subclass 23.1.
- X. Claim 30, drawn to the antibody, classified in class 530, subclass 387.1.

1. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-III, V, VII, are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, treat different patient populations and/or achieve different goals. These methods include administering agents that affect processing of laminin 5 by either BMP-1 or mTld, methods drawn to detecting protein activity, methods drawn to detecting protein expression, methods of screening and methods of treating various diseases. Therefore, a search and examination of all methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and/or the subject matter is divergent.

2. Inventions IV and I-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of treating disease or affecting processing can practiced with materially different products such as RNA.

Inventions VI and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method comprising detecting the expression of the protein can be practiced with materially different product such as a labeled binding protein.

Inventions VIII and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in different processes such as making antibodies.

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.06 for inventive groups that are directed to different

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products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups VI, VIII, IX, X are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The protein of Group VIII can be prepared by processes which are materially different from recombinant DNA expression of Group IX, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group IX can be used other than to make the protein of Group VIII, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group VIII can be used in materially different methods other than to make the antibody of Group X, such as in therapeutic or diagnostic methods (e.g., in screening). The antibody of Group X can be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immuno-chromatography), therapeutic methods or to isolated proteins. Lastly, the kit of Group VI can be used in diagnostic methods.

4. Inventions IV/VI,VII-X; VI/I-III,VII; VIII/I-III,V; IX/I-III,V,VII; X/I-III,V,VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the instant groups are not disclosed as capable of use together.

5. Claim 5 is generic to a plurality of disclosed patentably distinct species comprising epithelial cells. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Claim 7 is generic to a plurality of disclosed patentably distinct species comprising squamous cell carcinoma. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*RMD*

RMD

September 17, 2002

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER